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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,678	08/16/2001	Ronald H. Reeder	14538A005810	5058

20350 7590 04/09/2003

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,678

Applicant(s)

REEDER ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-24 and 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Self-Alignment

DETAILED ACTION

This application contains claims 6, and 25-38 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-44 are pending and Claims 6, and 25-38 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 1-5, 7-24, and 39-44 are examined on merits.

Claim Rejections - 35 USC § 112

Claims 1,2, 4, 7, 10-13, and 16-23 **remain rejected** and the new claims 39-44 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention.

Applicant argues that the necessary common attribute of the instantly claimed genus is the ability to hybridize to a polynucleotide encoding SEQ ID NO:2 under the recited condition; hybridization properties of nucleic acids are highly predictable in the art; because highly stringent conditions yield structurally similar DNAs, a person of ordinary skill in the art would not expect substantial variation among species encompassed within the scope of the claims. These arguments are not persuasive because the specification does not describe the identifying functional and structural characteristics of the hybridizing species encompassed by the scope of instantly claimed invention. The Office maintains hybridizing under the recited condition is not enough for satisfying written description requirement for structural characteristics of what is being claimed in relation to the limitation "a polynucleotide that codes for human RRN3 polypeptide" because the specification says that the human RRN3 cDNA is recently discovered by applicant and the terms human RRN3 is not well known in the art. The terms human RRN3 describing the gene or human Rrn3 recited in the claims

still read on an allelic variant or species homologs that the specification do not describe as stated in the previous Office action. Note the specification at pages 13 and 14. Further, the hybridizing species lack correlation between their structures to their function(s).

35 U.S.C. 112, First Paragraph, Scope Rejection

Claims 1,2, 4, 7, 10-13, and 16-23 **remain rejected** and the new claims 39-44 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling DNA encoding a protein to stimulate ribosomal RNA transcription, does not reasonably provide enablement for how to **use any other hybridizing nucleic acid molecules that do not encode a protein capable of stimulating ribosomal RNA stimulation**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant argues that instant invention is drawn to nucleic acid molecules encoding a protein that could be used in stimulating ribosomal RNA transcription but this argument is not persuasive because the argument is not commensurate in the scope of claims. The claimed nucleic acid species encompass nucleic acid molecules that do not necessarily encode a protein capable of stimulating ribosomal RNA transcription.

Claim Rejections - 35 USC § 101

Rejection of claims under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility **is withdrawn** because applicant's argument that SEQ ID NO:1 encodes SEQ ID NO:2 capable of stimulating ribosomal RNA transcription is credible. Use of the instant invention in stimulating ribosomal RNA transcription is substantial and specific to the protein encoded by the claimed product.

Rejection of claims under 35 U.S.C. 112, first paragraph, specifically, since the claimed invention is not supported by either a either a credible, specific and substantial asserted utility or a well established utility is also withdrawn because as stated above

under utility rejection that applicant's argument the utility of the nucleic acid encoding the protein capable of stimulating ribosomal RNA transcription is substantial, credible, and specific.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection affects all the claims depending from claims 1 and 7 as well.

Claims 1 and 7 are confusing because it is not clear what constitutes the scope of Rrn3 polypeptide based on the last three lines of claim 1 and lines 7-9 of claim 7. The recited limitation "wherein the Rrn3 polypeptide,a fragment thereof" appears to say that Rrn3 polypeptide is defined as any RNA Pol 1 transcription factor because "a fragment thereof" could be a single amino acid, therefore any RNA Pol 1 transcription factor such as Rrn6 shown at Figure 2 of Keys et al (IDS, 1996, Genes and Development, vol. 8 pages 2349-2362) could belong to Rrn3 polypeptide of the instant claims.

Claim 39, 40, 43, and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to **enable** one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims say that full complement of a nucleic acid molecule encoding a protein also encodes protein. The instant specification discloses the instantly claimed nucleic acid encodes a human protein. A complement of human DNA encoding a protein is called antisense DNA which does not usually encode a protein except in rare occasions and the specification does not teach the complement of a DNA encoding the protein also encode a protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/0549 (11 February 1999, pages 1, 201, and 202 only).

Claim 39 is interpreted as drawn to any nucleic acid molecule capable of hybridizing to SEQ ID NO:1. Note the claim construction of (d). WO 99/0549 teaches nucleic acid molecule capable of hybridizing to instant SEQ ID NO:1. Note the sequence alignment.

Allowable Subject Matter

SEQ ID NO:1 is free of art. However, the Office would like to remind applicant that US Patent Application Publication No. US2002/0146801 A1 (Oct. 10, 2002) with earlier filing date than that of the instant application, claims nucleic acids encompassed by instant claims 1, 2, 4, 10-13, 16-23, 39-44. Note claims 1-3, 6, 7, and 9 of US2002/0146801 A1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

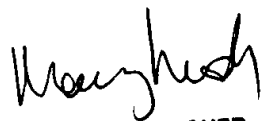
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

April 3, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1602

RESULT 10

ABAB3038 standard: DNA: 1461 BP.

ID ABAB3038 standard: DNA: 1461 BP.

AC ABAB3038:

05-FEB-2002 (first entry)

Human transcription factor TRFX-65 coding sequence.

Human: transcription factor; TRFX; cell proliferative disease;

autoimmune disease; inflammation; neurological disease;

developmental disorder; cancer; AIDS; infection; cytostatic; anti-HIV;

neuroprotective; anti-inflammatory; gene therapy; ds.

Human sapiens.

W0200172777-A2.

04-OCT-2001.

13-MAR-2001: 2001W0-NS08117.

13-MAR-2000: 2000US-0188986.

(INCYTE GENOMICS INC.

Hillman JL, Raughn MR, Yue H, Lal P, Lu DM, Patterson C;

Azimzai Y, Bandman O, Tang YT, Mathur P, Shah P, Au-Young J;

Reddy R;

WPI: 2001-570896/64.

P-PSDB: ABB50214.

Novel transcription factor polypeptides, used to treat diseases associated with altered activity and expression of TRFX, and to screen for agents capable of modulating its activity.

Claim 11: Page 299: 327pp: English.

The present sequence is the coding sequence for a human transcription factor. The transcription factor and its coding sequence are useful in the diagnosis, treatment and prevention of diseases associated with altered expression of the transcription factor e.g. cell proliferative, autoimmune/inflammatory, neurological and developmental disorders. A number of specific disorders/diseases are given in the specification, including: arteriosclerosis, cirrhosis, hepatitis, cancers, AIDS, allergies, anaemia, asthma, autoimmune thyroiditis, bronchitis, atopic dermatitis, diabetes mellitus, emphysema, Goodpasture's syndrome, gout, Graves's disease, multiple sclerosis, osteoarthritis, pancreatitis, psoriasis, rheumatoid arthritis, systemic lupus erythematosus, ulcerative colitis, uveitis, Alzheimer's disease, Huntington's disease, Parkinson's disease, stroke, and viral, bacterial, fungal and protozoal infections.

Sequence 1461 BP: 413 A: 335 C: 298 G: 415 T: 0 other:

Query Match

Best Local Similarity 20.38; Score 420.8; DB 22; Length 1461;

Matches 428; Conservative 0; Mismatches 12; Indels 0; Gaps 0;

1188 ttaaatggaattcgaagacacattttggaacatctcgtggaataatgacagacc 1247
1188 ttaaatggaattcgaagacacattttggaacatctcgtggaataatgacagacc 1247
530 ttaaatggaattcgaagacacattttggaacatctcgtggaataatgacagacc 589
1248 agtaatccatccatcgaagcgtcgtggaataatggaagccttttgacaga 1307
590 agtaatccatccatcgaagcgtcgtggaataatggaagccttttgacaga 649
1308 gataaatattatctcttattactgtaaaatcagctgaattcttggttaactgcg 1367
650 gataaatattatctcttattactgtaaaatcagctgaattcttggttaactgcg 709

QY 1368 cacatataccttaataaccagagattcggagaaagacacattcgcgaattgcctccat 1427
DB 710 cacatataccttaataaccagagattcggagaaagacacattcgcgaattgcctccat 1427
QY 1428 ggaacatttactcagcctcgcgaagctgtgtcttaaccttggttttgaacagagag 1487
DB 770 ggaacatttactcagcctcgcgaagctgtgtcttaaccttggttttgaacagagag 1487
QY 1488 cttttgagcggaaacctggaagaagtttgcagatctcgaagctgaatttaagcga 1547
DB 830 cttttgagcggaaacctggaagaagtttgcagatctcgaagctgaatttaagcga 1547
QY 1548 atagatgatagagcagcgaataatccctcgaagatttgcctgcctcagatgataat 1607
DB 830 atagatgatagagcagcgaataatccctcgaagatttgcctgcctcagatgataat 1607
QY 1608 gctgcaatcacaaataagta 1627
DB 950 gctgcaatcacaaataagta 969

RESULT 11

AAAX51663 standard: cDNA: 437 BP.

AAAX51663:

21-JUN-1999 (first entry)

Human secreted protein 5' EST SEQ ID NO:242.

Human: secreted protein; EST; expressed sequence tag; diagnosis;

forensic; gene therapy; chromosome mapping; signal peptide;

upstream regulatory sequence; cytokine activity; cell proliferation;

KW differentiation; haematopoiesis regulation; tissue growth regulation;

KW reproductive hormone regulation; chemotactic; chemokine; haemostatic;

thrombolytic; anti-inflammatory; tumour inhibition; ds.

Human sapiens.

W0906549-A2

11-FEB-1999.

31-JUL-1998: 98WO-1B01231.

01-AUG-1997: 97US-0905279.

(GENST) GENSET.

Duclert A, Dumas M, Line Edwards J, Lacroix R;

WPI: 1999-153779/13.

P-PSDB: AAY12885.

New nucleic acids encoding human secreted proteins - obtained from cDNA libraries derived from testis, ovary, uterus and spleen tissue.

Claim 1: Page 344-345; 522pp; English.

AAAX51459 to AAAX51691 represent 5' expressed sequence tags (ESTs) for human secreted proteins, and encode the proteins given in AAY1459 to AAY1691, respectively. The proteins given represent the signal peptide and an N-terminal fragment of a secreted protein. The nucleic acid sequences can be used for producing secreted human gene products. They can also be used to develop products for diagnosis and therapy. The proteins obtained may have cytokine activity, cell proliferation/differentiation activity, haematopoiesis regulation activity, tissue growth regulating activity, reproductive activity, chemotactic activity, chemokine activity, haemostatic activity, thrombolytic activity, receptor/ligand activity, anti-inflammatory activity, tumour inhibition activity or other activities. The products can be used in forensic, gene therapy and chromosome mapping procedures.

DR MPI: 2001-619362/13.
DR P-PSDB: ABG27804.
XX New isolated polynucleotide and encoded polypeptides, useful in
PT diagnostics, forensics, gene mapping, identification of mutations
PT responsible for genetic disorders or other traits and to assess
PT biodiversity.

Claim 1, SEQ ID No 27795; 103pp; English.

CC and gene mapping, and in recombinant production of (11). These polynucleotides are also used in diagnostics as expressed sequence tags for identifying expressed genes. (I) is useful in gene therapy technology for identifying expressed genes. (II) or to treat disease states involving to restore normal activity of (II) or to treat disease states involving quantitating a polypeptide in tissue, as molecular weight markers and as a food supplement. (II) and its binding partners are useful in medical imaging of sites expressing (II). (I) and (II) are useful for treating disorders involving aberrant protein expression or biological activities. The polypeptide and polynucleotide sequences have applications in diagnostics, forensics, gene mapping, identification of mutations responsible for genetic disorders or other traits to assess biodiversity and to produce other types of data and products dependent on RNA and amino acid sequences. AAS64197-AAS94564 represent novel human diagnostic coding sequences of the invention.

CC Note: The sequence data for this patent did not appear in the prior art specification, but was obtained in electronic format directly from WIT at ftp.wipo.int/pub/published_pct_sequences.

XX
Sequence 560 BP; 178 A; 96 C; 109 G; 177 T; 0 other;

Query Match 19.2% Score 398 DB 23 Length 500
Best Local Similarity 89.0% E-Val 1e-107
Matches 486: Conservative 0 Mismatches 56 Indels 4 Gaps

Oy 202 ccccaagaanaactgttcgattcgaatgcagaaacatgcacaatacttcatcgagtgcacaa 1
Db 1 cccaagaanaactgttcgaatttgtgcgaactatcacadaagcttttgatcaaatgaaa 1

262 agggatgaacaacatgaccttgcattgtgcgaagaacacacatatatgatgcagatgaaat 262

[illegible]